IS 11364 (1994): Anaesthetic Reservoir Bags [MHD 13: Veterinary Hospital Planning and Surgical Instruments]

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ISO 5362 : 1986
(Reaffirmed 2006)

भारतीय मानक

संवेदनहारी द्रव्य रखने की थैलियाँ — विशिष्टि

(पहला पुनरीक्षण)

Indian Standard

ANAESTHETIC RESERVOIR BAGS — SPECIFICATION

(First Revision)

UDC 615.471 : 616 - 089.5 : 614.894

BUREAU OF INDIAN STANDARDS
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NEW DELHI 110 002

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Price Group 2

NATIONAL FOREWORD

This Indian Standard, which is identical with ISO 5362-l 986 'Anaesthetic reservoir bags', issued by the International Organization for Standardization (ISO), was adopted by the Bureau of Indian Standards on the recommendation of the Anaesthetic, Resuscitation and Allied Equipment Sectional Committee and approval of the Medical Equipment and Hospital Planning Division Council.

This standard was first published in 1985 as a dual number Indian Standard corresponding to ISO 5362-i 980 'Anaesthetic reservoir bags'. It has been revised with a view to incorporate the modifications effected in the first edition of ISO 5362 brought out in 1986, namely, to cover a suitable design of neck for use with the breathing attachments of 15 mm size and to exclude the requirements for material from the standard and cover them as recommendatory in the form of an Annex.

The text of the above mentioned ISO standard has been approved as suitable for publication as Indian Standard without deviations. Certain conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.
b) Comma (,) has been used as a decimal markerwhile in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this standard, the following International Standards are referred to. Read in their respective place the following :

international Standard	*Corresponding Indian Standard*	*Degree of Correspondence*
ISO 2878 Rubber vulcanized — Antistatic and conductive products — Determination of electrical resistance	IS 3400 (Part 15) : 1971 Method of test for vulcanized rubbers : Part 15 Volume resistivity of electrically conducting and antistatic rubbers	Technically equivalent
ISO 5356 Breathing attachments for inhalation anaesthetic apparatus, lung ventilators and resuscitators Part 1: Conical fittings and adopters for breathing systems (since published) Part 2 : Screw-threaded weight-bearing fiiings (since published)	IS 7409 : 1985 Breathing attachments for anaesthetic apparatus *(first revision)*	Technically equivalent
IEC Publication 601-l Safety of medical electrical equipment — Part 1 : General requirements	IS 13450 (Part 1) : 1993 Medical electric equipment : Part 1 General requirements for safety, Section 1 General	Identical

ISO *2882* 'Rubber vulcanized — Antistatic and conductive products for hospital use — Electrical resistance limits', appearing in the normative reference of this standard does not have the corresponding Indian Standard. The Anaesthetic, Resuscitation and Allied Equipment Sectional Committee has, therefore, decided that it is acceptable for use in conjunction with this standard.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calucalated, expressing the result of a test, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (revised)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in the standard.

Indian Standard

ANAESTHETIC RESERVOIR BAGS — SPECIFICATION

(First Revision)

0 Introduction

This International Standard is one of a series dealing with anaesthetic equipment and medical breathing machines and is supplementary to ISO 5355. This International Standard is primarily concerned with the design of the neck, size designation and 'compliance of anaesthetic reservoir bags.

The requirement that reservoir bags should be electrically conductive when used with flammable anaesthetic is widely recognized and is of particular importance when such bags are rhythmically compressed by the anaesthetist in order to provide intermittent positive pressure ventilation. Little is known about the extent of any possible fire or electrical hazards associated with the use of electrically conductive bags. While such bags reduce explosion hazards due to the generation of static electricity, they may give rise to other electrical hazards.

While it remains desirable to use conductive bags in normal anaesthetic practice, the widespread use of non-flammable anaesthetics, the development of new materials which might be used for disposable (single-use) bags and an appreciation of the possible hazards referred to above have together created a new situation. Therefore, in order to avoid restricting the development of new products it was considered undesirable to exclude non-antistatic (non-conductive) bags from this International Standard. However, such non-conductive bags should NEVER be used in the presence of flammable vapours.

Recommendations for materials are given in the annex.

1 Scope and field of application

This International Standard specifies requirements for reservoir bags for use with anaesthetic or breathing apparatus. It is concerned with the design of the neck, size designation, compliance and, where relevant, requirements for electrical conductivity.

Special purpose bags, for example bellows and self-expanding bags, are excluded from the *scope* of this International Standard.

2 References

ISO 2878, *Rubber, vulcanized — Antistatic and conductive products — Determination of electrical resistance.*

ISO 2882, *Rubber, vulcanized — Antistatic and conductive products for hospital use — Electrical resistance limits.*

ISO 5355, *Breathing attachments for inhalation anaesthetic apparatus, lung ventiiators and resuscitators —*

Part 1: Conical fittings and adaptors for breathing systems. [1)]

Part 2 : Screw- threaded weight-bearing fittings. [1)]

IEC Pu biication 601-1, *Safety of medical electrical equipment — Part 1 : General requirements.*

3 Definition

anaesthetic reservoir bag : Collapsible container from which the patient may draw his tidal volume.

4 Leakage

The bag shall be free from leaks.

5 Size designation

The size of the bag shall be designated by the nominal capacity expressed in litres.

6 Preferred sizes

It is recommended that the range of preferred sizes should be 0.5 — 1 — 1,5 — 2 — 3 and 5 litres.

7 Capacity

The capacity of the bag shall be subject to a tolerance of ± 15 % of the nominal capacity when tested according to the procedure outlined below.

Place the bag in a tank of water, the lower opening of the bag, if present, being sealed. Hold the bag vertically with the top rim of the opening held 25 mm above the surface of the water in the tank. Fill the bag with water. Then measure the volume of water contained in the bag.

1) At present at the stage of draft.

8 Neck

8.1 Neck for connecting to conical fittings of 22 mm size

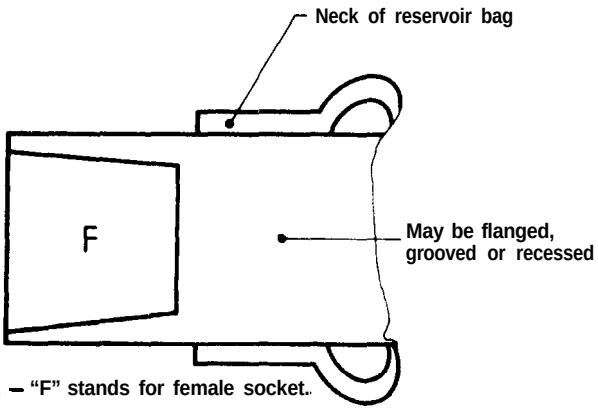
The bag shall be adequately reinforced at the neck and shall be constructed to give a satisfactory fit on male conical fittings of 22 mm size in accordance with ISO 5356/1.

The axial length of the neck of bags designed to fit 22 mm male conical fittings shall be not less than 25 mm, and not more than 35 mm.

8.2 Neck designed for use with breathing attachments of 15 mm size

The bag shall be adequately reinforced at the neck and shall be constructed to give a satisfactory fit on male conical fittings of 15 mm size in accordance with ISO 5356/1.

Alternatively, the bag shall have a plain (unreinforced) neck suitable for mounting on an adaptor of which the cylindrical portion has a diameter of 18 mm and an axial length of approximately 18 mm in accordance with the figure.



NOTE – "F" stands for female socket.

Figure – Adaptor for connection to reservoir bags

8.3 Neck reinforcement

Any reinforcement at the neck of the bag involving the use of separate components shall provide continuous secure attachment under conditions of normal use, as for example, when the bag is used for manual intermittent positive pressure ventilation.

8.4 Neck design

The body and neck shall be designed and assembled in such a way that they may not effect a valve-like action under normal conditions for use.

9 Pressure-volume test

Under the conditions described below, the pressure head of water shall be not less than 30 cmH_2O and shalt not exceed 50 cmH_2O at any time during the test. After this test the bag shall revert within 30 min to its original capacity within a tolerance of $+ {}^{10}_{0}$ % on the actual capacity.

Place the bag in a tank of water, the lower opening of the bag, if present, being sealed. Hold the bag vertically with the top rim of the opening held 25 mm above the surface of the water in the tank. Fill the bag with water within a period of 5 min. Connect to the neck of the bag a bung of appropriate size through which a tube of not less than 10 mm bore is inserted, and of sufficient length to give a pressure head of 50 cmH_2O. Add water by means of a funnel through the tube connected to the bag in order for the volume of water to correspond to four times the nominal capacity of the bag. Determine the pressure head.

The test shall be conducted with water at a temperature of 20 ± 3 °C.

NOTE – The electrical conductivity of a bag which has undergone this test may be reduced, and may result in failure to meet requirements of the appropriate electrical resistance tests.

10 Electrical conductivity

The electrical characteristics of bags made of electrically conductive material for use with flammable anaesthetic agents shall be specified and tested in accordance with ISO 2878 and ISO 2882 respectively, or with the requirements of the appropriate national authorities.

11 Marking

The marking shall be legible and durable and shall include the following :

a) the name or trade-mark of the manufacturer and/or supplier;

b) the nominal capacity (see clauses 5 and 7);

c) anaesthetic reservoir bags made of conductive material shall be marked in accordance with IEC Publication 601-I;

d) anaesthetic reservoir bags made of conductive material shall be coloured black, and those made of non-conductive material shall be of any colour except black.

NOTE – It is recommended that reservoir bags should be additionally marked with the date (month and year) of manufacture.

Annex

Recommendations for materials

(This annex does not form an integral part of the standard.)

A.1 The bag should be made of suitable material which should be reasonably resistant to anaesthetic agents.

A.2 Unless designated for single use, the bag should be reasonably resistant to deterioration by methods of cleaning, disinfection and sterilization as recommended by the manufacturer or supplier. It is desirable that such products should withstand accepted methods of steam sterilization.

A.3 The sheeting forming the body of the bag should be pliable and remain reasonably distensible when the bag is inflated to its nominal capacity.

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